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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
|-----------------|-------------|----------------------|---------------------|
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09/555,362 07/24/00 BRADFIELD

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HM22/0928

EXAMINER

BASKAR, P

ART UNIT

PAPER NUMBER

1645

DATE MAILED:

09/28/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

**Office Action Summary**

Application No.

09/555,362

Applicant(s)

BRADFELD ET AL.

Examiner

Padmavathi v Baskar

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1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-43 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-43 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____.  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____. | 6) <input type="checkbox"/> Other: _____                                    |

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### RESTRICTION

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-6, 8-20, 24, 27, 30-32, 34-37, 39 drawn to an isolated nucleic acid molecule, further election of species required

Group II, claim(s) 7, 21, 25, 26, 28, 29, 33 and 38 drawn to isolated proteins, further election of invention required

Group III, claim(s) 22-23 drawn to an antibody, further election of invention required

Group IV, claim(s) 40-41 drawn to a method for determining if a test compound regulates circadian function, Further election of invention required

Group V, claim(s) 42-43 drawn to a method for determining if a test compound regulates red blood cell synthesis, Further election of invention required

2. The inventions listed as Groups I-V do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Group I is directed to an isolated nucleic acid molecule that encodes protein selected from the group consisting of MOP2, MOP3, MOP4, MOP5, MOP6, MOP7, MOP8, MOP9, which is the first product. However, because Hogenesch et al disclose (Figure 2) an isolated nucleic acid molecule that encodes protein MOP2, no special technical feature exists for Group I as defined by PCT Rule 13.2, because it does not define a contribution over the prior art. The technical features of Groups II-III are drawn to different products namely protein (amino acid) and antibody with (additionally has affinity and avidity that a protein is not capable of having)

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different structure and function, which do not require each other for their practice and do not share the same or a corresponding technical feature. Groups IV and V are different methods having different goals, method steps and starting materials, which do not require each other for their practice and do not share the same or a corresponding technical feature. Note that PCT Rule 13 does not provide for multiple products or methods within a single application. Because the technical feature of Group I is not a special technical feature, and because the technical features of the Group II-V inventions are not present in the Group I claims, unity of invention is lacking

### Distinct Inventions

3. This application contains several groups of inventions and each group consists more than one invention (i.e., multiple). These inventions are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The inventions are as follows:

**Nucleic acids or proteins**, MOP2, MOP3, MOP4, MOP5, MOP6, MOP7, MOP8 and MOP9; (SEQ.ID.NO: 2-9 or 11-18, If applicant elects any one of these groups, then applicant is required to elect any one SEQ.ID.NO).

**Antibodies** to MOP2, MOP3, MOP4, MOP5, MOP6, MOP7, MOP8 and MOP9; (If applicant elects this group, then applicant is required to elect any one antibody to be selected).

**Methods using different nucleic acids** using MOP2, MOP3, MOP4, MOP5, MOP6, MOP7, MOP8 and MOP9 (If applicant elects this group, then applicant is required to elect one method using one nucleic acid to be selected).

4. Applicant is required, in reply to this action, to elect any one MOP2, MOP3, MOP4, MOP5, MOP6, MOP7, MOP8, MOP9 from one Group and identify one SEQ.ID.NO to which the

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claims shall be restricted. The reply must also identify the claims readable on the elected invention, including any claims subsequently added. If applicant elects one SEQ.ID.NO from this group, associated sequences, which share the common structure or overlap the sequence Of that SEQ.ID.NO (epitopes) will be examined. Applicant is advised to elect one SEQ.ID.NO and identify the associated sequence, which share the common structure or overlap the sequence of that SEQ.ID.NO with specific amino acid or nucleic acid or antibody or method.

5. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

6. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

8. The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).

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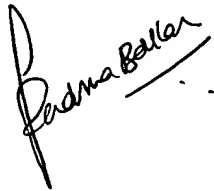
Misnumbered claim 40 (second time recited after claim 41) <sup>has</sup> been <sup>is</sup> renumbered <sup>42</sup> 42.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Padmavathi v Baskar whose telephone number is (703) 308-8886. The examiner can normally be reached on M-F (6:30A.M-4: 00 P.M.) First Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (703) 308-3909. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

P. Baskar Ph.D.  
9/28/01

A handwritten signature in black ink, appearing to read "Padma Baskar", with a horizontal line underneath the name.